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Honors Research Projects

The Dr. Gary B. and Pamela S. Williams Honors College

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Mangled Extremity Simulator

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I. Abstract:

A mangled extremity is defined as a limb with serious injury to three of its four physiological systems: integumentary, muscular, vascular, and skeletal. Trauma programs across the country do not see mangled extremity victims very often; however, a mangled extremity is a prevalent injury seen in a military setting. As the military continues to develop better systems for mangled extremity patients, amputation rates are decreasing, but these systems and the corresponding training are lacking in the civilian setting. A need exists for a simulator that would allow civilian trauma surgeons, residents, and students to better learn the algorithms necessary to take care of the different ways a mangled extremity may present and then decide whether to repair the mangled limb or amputate, as well as allow for the practice of appropriate surgical procedures to be performed.

Team Medivations has designed a simulator to be utilized by trauma programs for the training of surgeons for mangled extremity cases. The design consists of two main parts, an upper and lower leg that will connect via a push pin device in order to allow for multiple mangled injuries of the lower leg to be simulated. The upper leg will be a housing unit for the pump components, and the lower leg will undergo the trauma and surgery. Components of the simulator include foam cortical shell bones that when mangled can be repaired using internal fixation devices, synthetic musculature and skin made from 100% silicone rubber, an outer skin layer made of liquid latex, and a peristaltic 3D-printed pump with latex tubing to mimic pulsatile flow of the vasculature system. A prototype is in the process of being built, and future testing of the simulator is planned in order to determine the efficacy of the design.

II. Introduction:

A mangled extremity is defined as a limb with serious injury to three of its four physiological systems: the integumentary or skin, muscular, vascular, or skeletal systems. In trauma programs across the country, the most common cases of mangled extremities are crush injuries to the lower leg that are a result of vehicular, industrial, or farm accidents (1). Trauma injuries consisting of a mangled extremity do not often occur in civilian areas, and therefore surgeons and care providers do not have the adequate experience to efficiently handle this situation. The rate of amputation would decrease if trauma surgeons had more opportunities to practice management and treatment of the mangled extremity. Currently, there is a lack of inexpensive surgical training simulators for mangled extremities which has led to very limited training. If there was a simulation system that could accurately represent human anatomy, model the physiology of many different crush injuries, and allow for extensive practice of trauma surgery, surgeons could have a more effective training experience and be able to provide better patient care.

As a group of biomedical engineers, Team Medivations, together with Tiffany Marchand, MD, and Michelle Chapman, BS Manager of Summa Center Preclinical Research and Surgical Skills Training, of Summa Health Systems, was tasked with designing and constructing a realistic, workable, surgical simulator that would better prepare surgeons and care providers to handle a mangled extremity situation.

III. Background Information:

Team Medivations performed research prior to designing the mangled extremity simulator in order to determine what type of injuries typically occur with a mangled extremity, what simulation devices are patented and currently on the market, and the design issues with the current simulators.

The most common mangled extremity cases are ones in which the limb has been destroyed by sources that cause major damage to the exterior and interior of the limb, or where the limb is completely removed. These cases are more common in military combat zones and are not usually seen around civilian areas (2). The most common cases seen in civilian trauma programs are crush injuries, an injury caused by something that places high forces on the limb causing severe damage, typically below the knee and above the ankle. Mangled extremities come in all severities which makes determining what type of surgery to perform a difficult task by surgeons. Currently there is a scoring system developed to aid with classifications of these different severities named the Mangled Extremity Severity Score (MESS) (3). This scoring system is designed to estimate the severity of a limb after trauma. Although this system helps to rank the severity of the injury, it doesn't necessarily assist the surgeon in determining what type of surgery to perform (4).

Currently, there are many patents for surgical simulators, but only a few deal with extremities, and even fewer that deal with extreme trauma to the extremities. The HemaSTaT training simulator from Simulation, Inc. is the only simulator currently in use and similar in design. This system is designed to train and evaluate the skills of military medical personnel in terms of blood loss and control of hemorrhage by teaching the application of tourniquets or the use of hemostatic agents to induce clotting (5).

IV. Project Objectives and Goals:

Preliminary design ideas focused on the functional requirements provided by the customer. These requirements were separated into two categories. The first dealt with what the customer wanted the simulator to accomplish. As stated earlier, Team Medivations' simulator would better prepare surgeons and care providers to handle a mangled extremity situation. Blood flow must occur so that the surgeon is able to find a pulse and learn to deal with the associated vascular issues that arise when a blood vessel is damaged. It is also important to understand what happens to the other systems in the extremity as well. The muscles, for example, will retract into the limb when severed. To simulate this, the trainer will have muscles made from a material that is elastic and will retract.

Secondary requirements for the simulator are the physical elements such as the anatomical features. The device must have bones, muscles, and major blood vessels with textures and dimensions similar to that of human tissue. Authenticity requires the size, weight, and type of material to be very similar to a real leg. It is imperative that the simulator matches human anatomy in order to keep the procedure as close to protocol as possible. The customer requested the simulator to be a normal male adult leg. This will keep the simulator more realistic and allow the learner to identify key anatomical landmarks in an otherwise imperfect model. Again, not every aspect can be exactly the same. There will be more space than anatomically correct be between the skin, muscles, and bones because of the lack of vasculature, fluid, and other tissues that are found in normal anatomy.

The goals for this project are to account for both the functional and physical requirements mentioned. This device will meet the demands of the customer by being able to provide a simulation of an actual mangled extremity injury. The project should cost no more than $500, and will be completed in approximately six months. The simulator will be lifelike, and all electrical and mechanical components will be included. A pump will provide a pulsatile flow so that a pulse can be found in the ankle. The ultimate hope is that after the completion of the product, trauma surgeons will be able to provide the best possible care for their patients and amputation will become only a secondary option.

All preliminary design ideas and dates are shown in the Objective tree (Appendix B) and the Gantt Chart (Appendix C) respectively.

V. Materials and Methods:

Team Medivations' mangled extremity simulator prototype is being produced using silicone rubber, latex rubber, a composite bone, and multiple other materials. The simulator reproduces accurate physiological functions from realistic muscles to pulsatile blood flow. Surgeons will be able to cut, suture, and perform the actual procedures used during the reconstruction of a mangled extremity . Unfortunately, parts of the device are not reusable; however, its unique design allows for interchangeability of used parts for new parts. Because of its flexible design, surgeons can be challenged with a number of different scenarios to learn from, allowing them to gain knowledge and experience they need in order to provide a patient with the best possible chances of limb recovery.

The simulator is being constructed in two parts: upper thigh to above the femoral condyles, and from the femoral condyles to the foot. The upper portion of the simulator will house the pump, wires, and a reservoir for the circulated blood, as well as any other items the customer wants it to contain (i.e. surgical equipment, etc.). The lower portion is where the crush injury will be simulated. It will contain all four physiological systems, including a pulse that can be felt posteriorly to the medial malleolus on the foot. The skin and muscles were made out of 100% silicone rubber, and the skin will be layered with a latex coating to mimic both the feel and color of skin. The silicone rubber will provide the thickness of the different layers of the skin. The bones were purchased as a pre-assembled full left leg from Sawbones and are foam cortical shell (Figure 1). The bone will be wrapped in a layer of silicone that has been cut into the anatomical shapes of the muscles. No bones or muscles will be placed in the foot as the foot is not a pertinent part of the simulation at this time.

In order to begin constructing the limb, a plaster mold was formed using one of the team member's left leg (Figure 2). The leg was molded in two parts; a foot that included the ankle and an ankle to mid thigh section. The ankle to thigh extremity was covered in plaster wrap, set to dry, and then removed by cutting from the top of the plaster leg down to the ankle and pulled off. The mold was then filled with 11.5 pounds of plaster and cast (Figure 3). After the plaster casting of the leg had dried, it was sanded to create a smooth outer surface (Figure 4). Silicone rubber was painted onto the cast of the leg, covering the whole limb as the first layer of skin (Figure 5). To mold the foot, MoldGel alginate was poured into a rectangular container and the team member's left foot was lowered into the alginate to cast a mold. Once the alginate was set, silicone was pumped into the mold (Figure 6). Tubing for vascular flow was inserted near the ankle and the mold was left to dry. Muscles were created using two different techniques. The first method involved sculpting clay into the shape of the gastrocnemius and soleus muscles and then wrapping the clay with plaster wraps to create a mold. Once the mold was dry, the clay was removed and the mold was filled with silicone to create the muscles (Figures 7 and 8). The second method used for the anterior lower leg muscles required pouring silicone onto a cookie sheet to create a rectangular silicone sheet. The silicone sheet was then partially cut at three locations in a vertical direction to create the tibialis anterior, extensor digitorum longus, and the fibularis longus muscles (Figure 9).

The vascular system will be created using latex rubber tubing 3/8 inches in diameter that runs through a pulsatile pump propelled by a 6-volt motor (Figures 10 and 11). The tubing will only simulate the major blood vessels with the exception of some vessels branching off from the femoral arteries, and will be connected to a reservoir located in the upper thigh of the leg. A peristaltic pump was chosen to create a pulsatile flow because the arms of the rotor can vary in length causing different pressures while the fluid passes through the tubing. Another advantage of using a peristaltic pump is that it does not come into contact with the liquid, or blood. This prevents blockage or buildup and allows for easier repairs. Due to the pump's compact design, it was modeled in a computer-aided design software package called Creo Parametric. Upon finalizing the design, the pump was then printed on a Makerbot 3D printer and assembled together to be tested. The venous system will not be able to be simulated in this model.

The sections of the simulator will be attached using a system of push pins. This will allow the removal and replacement of the lower leg training section. Surgeons will be able to experience a multitude of different crush injury types depending on how the leg is mangled. Reuse of the lower limb that has been mangled and repaired will be nearly impossible in this, design; however the pump, as well as the other equipment housed in the upper leg will be reusable.

VI. Future Directions:

Team Medivations is still in the process of constructing the prototype, however the individual components are completed and the bulk of the remaining work needed is the assembly. The latex tubing will need to be branched throughout the limb in order to mimic the correct anatomical vasculature. The pump and the reservoir for the circulated blood will need to be housed in the upper thigh and connected to the lower leg. After the muscles are attached to the bone and the silicone skin has been placed, a layer of latex will be painted on the silicone as well as the hollow thigh and foot in order give the skin a realistic feel and color and to cover up any seams or rough spots. The device that will connect the foot, lower leg, and upper thigh still needs to be purchased and incorporated into the leg. To finalize the project, the pump will need to be tested to check for any leakage into the limb, and a pulse will need to be detected in the ankle in order to comply with the realistic nature of simulation.

In the future, if this design was used to manufacture a mangled extremity simulator, better materials should be utilized. Synthetic skin, muscles, and vasculature from SynDaver Labs could be used to better represent the human anatomy and physiology. The interstitial space of the limb between the muscles and the skin will also be filled to better simulate what happens to internal structures after trauma is experienced. Ultimately, a reusable product will be created to allow multiple surgeries on one device, making it a very low-cost investment. A better design for the anatomical structures and physiological functionalities will be needed to provide as lifelike a model as possible more so than the first prototype. Possible trauma to the upper leg may then be introduced, even though thigh area trauma is not very common compared to the lower leg, which contains the foot and ankle regions. Foot trauma will be a more plausible innovation to this design because replacement tips could be designed and attached to allow for foot trauma simulations. This would require the inclusion of bone, muscle, and the vascular anatomy of the foot and would be able to attach to the lower leg.

VII. Discussion:

The mangled extremity simulator aims to help trauma surgeons gain more experience and skills needed to perform surgical procedures for a mangled extremity in a civilian setting. The design of this surgical training simulator is such that it can adapt to different scenarios as well as being changed in the future.

During the material-purchasing process, there were problems that arose concerning the budget that was given. Most of the products used in normal simulator designs are too expensive, so a design utilizing cheaper materials was adopted. The team's initial idea was to use gel wax to construct the muscles, but problems were foreseen concerning the attachment process. In order to get the material to adhere it would need to be heated; however, heating the gel wax would cause the rest of the muscles to deform and lose shape. The next material choice was an acrylic based silicone, which was normally used for drywall and sealing leaks. Because this material was not 100% silicone, when it dried it did not have the texture nor the stability needed in order to make the muscles. The last material issue was with the selection of tubing for the vascular component. The first choice was airline tubing, which turned out to be too stiff for the arms of the pump and kept pulsatile flow from reaching the ankle.

Throughout the building process many other roadblocks became apparent other than the material selection. The team's initial plan for creating skin was to paint liquid latex onto a team member's leg and peel it off, so that it could later be placed on the simulator. This proved difficult because drying time between applications of layers was long and not enough time was given before removal. Because of this, the latex was stuck to the skin of the group member's leg, causing it to rip in places and fold over on itself.

The problems continued during the pump design when the size of the pump was too small and the end did not fit correctly. This caused the pump to rip and break in places. On the second attempt for the pump, the arms of the rotor were too long to create pulsatile flow. After the final modification of the pump, work began on the muscles. The first attempt at making muscles involved wrapping clay molds of the muscles in plaster wraps similar to the ones used on the model leg, and then filling them with silicone. There wasn't enough airflow to the silicone which made drying a long process. The second attempt involved filling a short, thin container with a layer of silicone and then cutting the muscle designs into it, which will be attempted in the following days.

Although the prototype is not yet complete, Team Medivations is working diligently to finalize the project and have it ready for testing. Since the customer wishes to mangle it themselves, they will be the ones to test the simulator. It is hoped that this project meets the customer's expectations and provides exceptional teaching skills to the surgeons that will be using it.

VIII. Appendices:

Appendix A.

Figure 1. Full left leg skeletal model group purchased from Sawbones.

Figure 2. Plaster wrap mold of member's leg being prepared for plaster casting

Figure 3. Plaster models of left foot and leg prior to sanding.

Figure 4. Plaster models of left foot and leg sanded and prior to silicone application.

Figure 5. Plaster cast of left leg after full silicone skin layer had been applied.

Figure 6. Alginate mold containing silicone cast of left foot.

Figure 7. Modeling clay molds of the muscles (starting from left to right) plaster wraps of the Tibialis Anterior and Extensor Digitorum Longus muscles, modeling clay casts of the aforementioned, and a modeling clay cast of the soleus. Left two models are no longer being used.

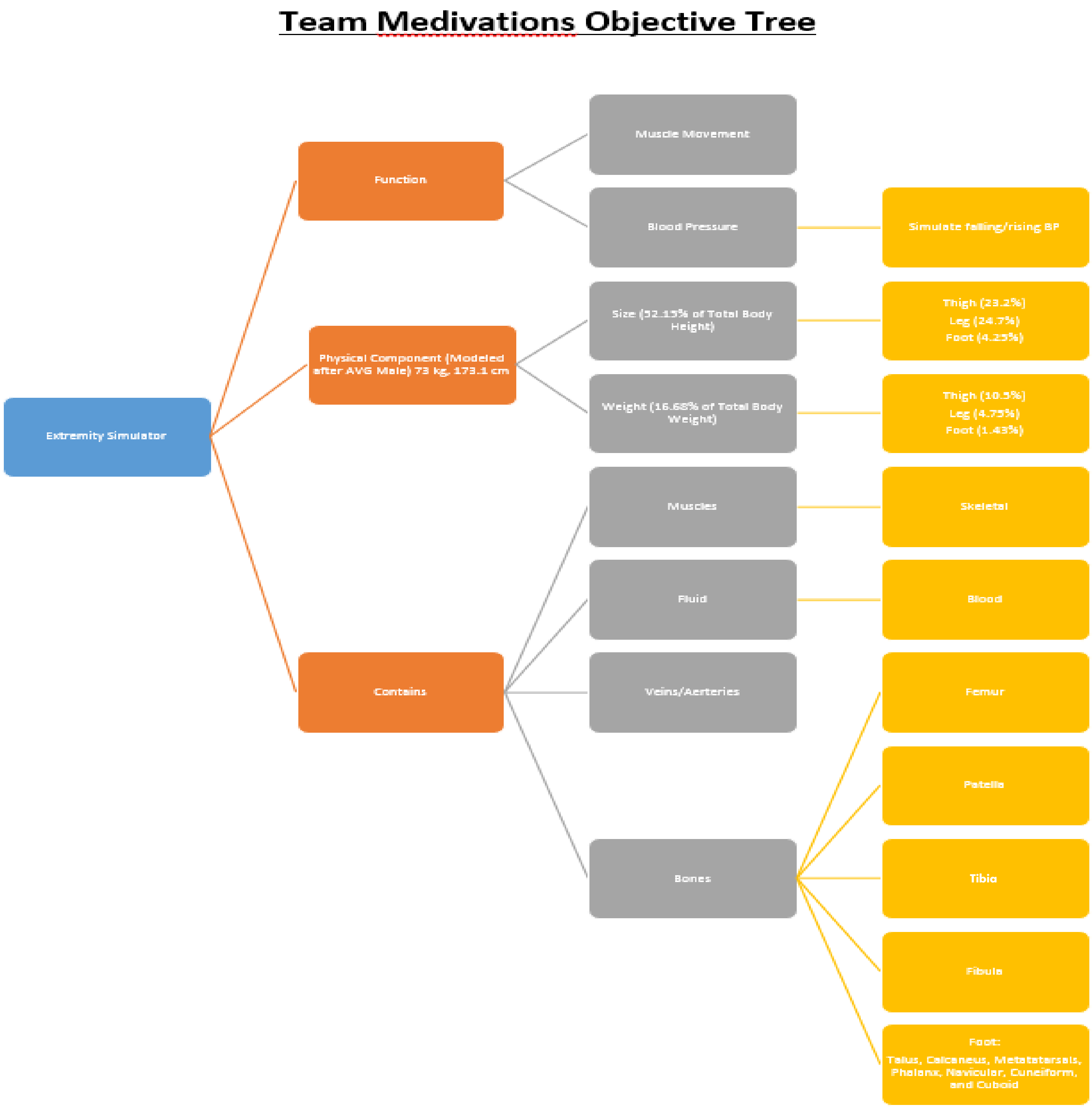
Figure 8. Plaster wrap mold and silicone casting of the model for the Gastrocnemius (left) and Soleus (right) of the left leg.

Figure 9. (From top to bottom) Silicone for the muscle drying on flat surface. Distal portion of leg after silicone was applied. Plaster mold of the Soleus.

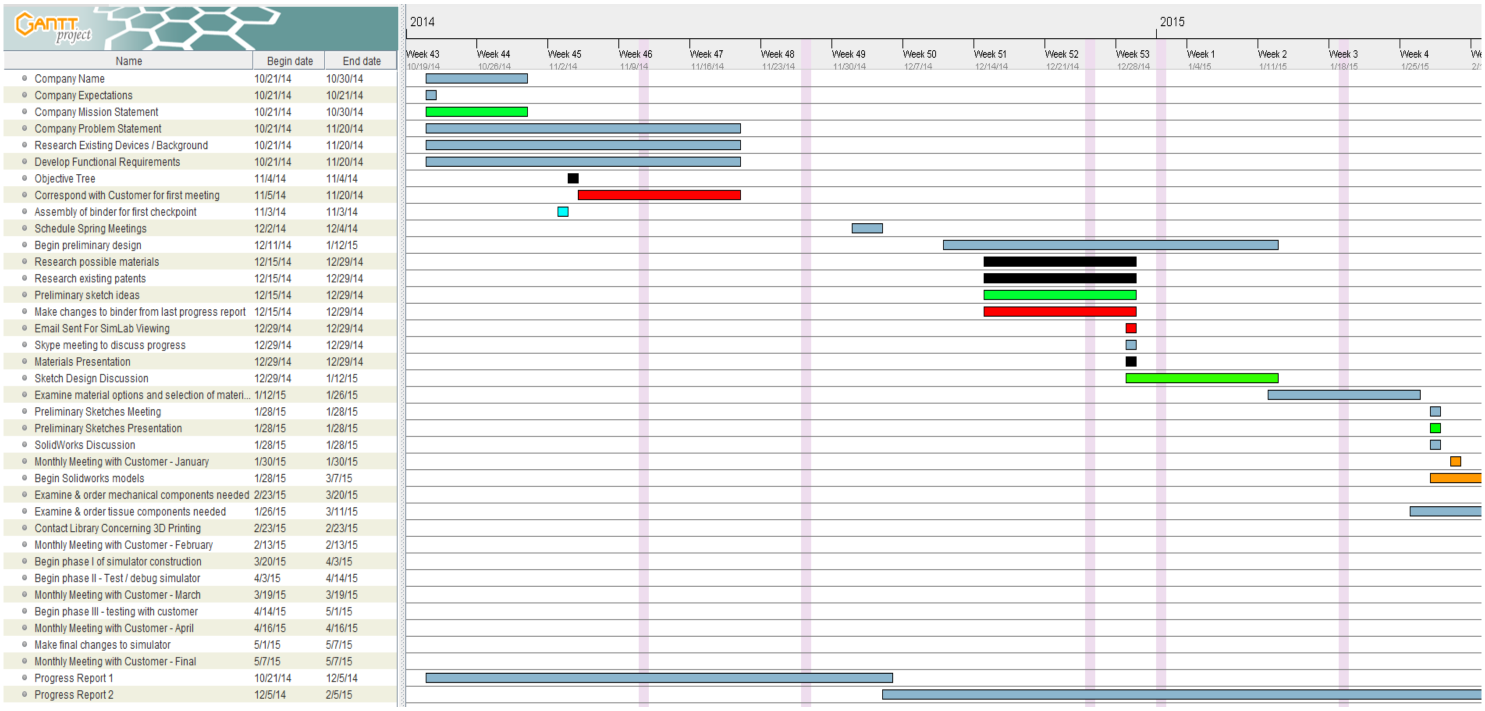
Figure 10. Parts to the pulsatile pump that will circulate blood flow through the leg as well as the tubing that will be inserted into the pump (yellow) and will act as the vasculature.

Figure 11. Fully assembled pulsatile pump with tubing for vasculature ran through both ends.

Appendix B.


Team Medivations Objective Tree
Extremity Simulator
Function
Physical Component (Modeled after AVG Male) 73 kg, 173.1 cm
Contains
Muscle Movement
Blood Pressure
Size (52.15% of Total Body Height)
Weight (16.68% of Total Body Weight)
Muscles
Fluid
Veins/Aerteries
Bones
Simulate falling/rising BP
Thigh (23.2%)
Leg (24.7%)
Foot (4.25%)
Thigh (10.5%)
Leg (4.75%)
Foot (1.43%)
Skeletal
Blood
Femur
Patella
Tibia
Fibula
Foot:
Talus, Calcaneus, Metatatarsals, Phalanx, Navicular, Cuneiform, and Cuboid

Appendix C.


GANTT project
Name | Begin date | End date
2014
2015
Week 43 Week 44 Week 45 Week 46 Week 47 Week 48 Week 49 Week 50 Week 51 Week 52 Week 53 Week 1 Week 2 Week 3 Week 4
Company Name 10/21/14 10/30/14
Company Expectations 10/21/14 10/21/14
Company Mission Statement 10/21/14 10/30/14
Company Problem Statement 10/21/14 11/20/14
Research Existing Devices / Background 10/21/14 11/20/14
Develop Functional Requirements 10/21/14 11/20/14
Objective Tree 11/4/14 11/4/14
Correspond with Customer for first meeting 11/5/14 11/20/14
Assembly of binder for first checkpoint 11/3/14 11/3/14
Schedule Spring Meetings 12/2/14 12/4/14
Begin preliminary design 12/11/14 1/12/15
Research possible materials 12/15/14 12/29/14
Research existing patents 12/15/14 12/29/14
Preliminary sketch ideas 12/15/14 12/29/14
Make changes to binder from last progress report 12/15/14 12/29/14
Email Sent For SimLab Viewing 12/29/14 12/29/14
Skype meeting to discuss progress 12/29/14 12/29/14
Materials Presentation 12/29/14 12/29/14
Sketch Design Discussion 12/29/14 1/12/15
Examine material options and selection of materi... 1/12/15 1/26/15
Preliminary Sketches Meeting 1/28/15 1/28/15
Preliminary Sketches Presentation 1/28/15 1/28/15
SolidWorks Discussion 1/28/15 1/28/15
Monthly Meeting with Customer - January 1/30/15 1/30/15
Begin Solidworks models 1/28/15 3/7/15
Examine & order mechanical components needed 2/23/15 3/20/15
Examine & order tissue components needed 1/26/15 3/11/15
Contact Library Concerning 3D Printing 2/23/15 2/23/15
Monthly Meeting with Customer - February 2/13/15 2/13/15
Begin phase I of simulator construction 3/20/15 4/3/15
Begin phase II - Test / debug simulator 4/3/15 4/14/15
Monthly Meeting with Customer - March 3/19/15 3/19/15
Begin phase III - testing with customer 4/14/15 5/1/15
Monthly Meeting with Customer - April 4/16/15 4/16/15
Make final changes to simulator 5/1/15 5/7/15
Monthly Meeting with Customer - Final 5/7/15 5/7/15
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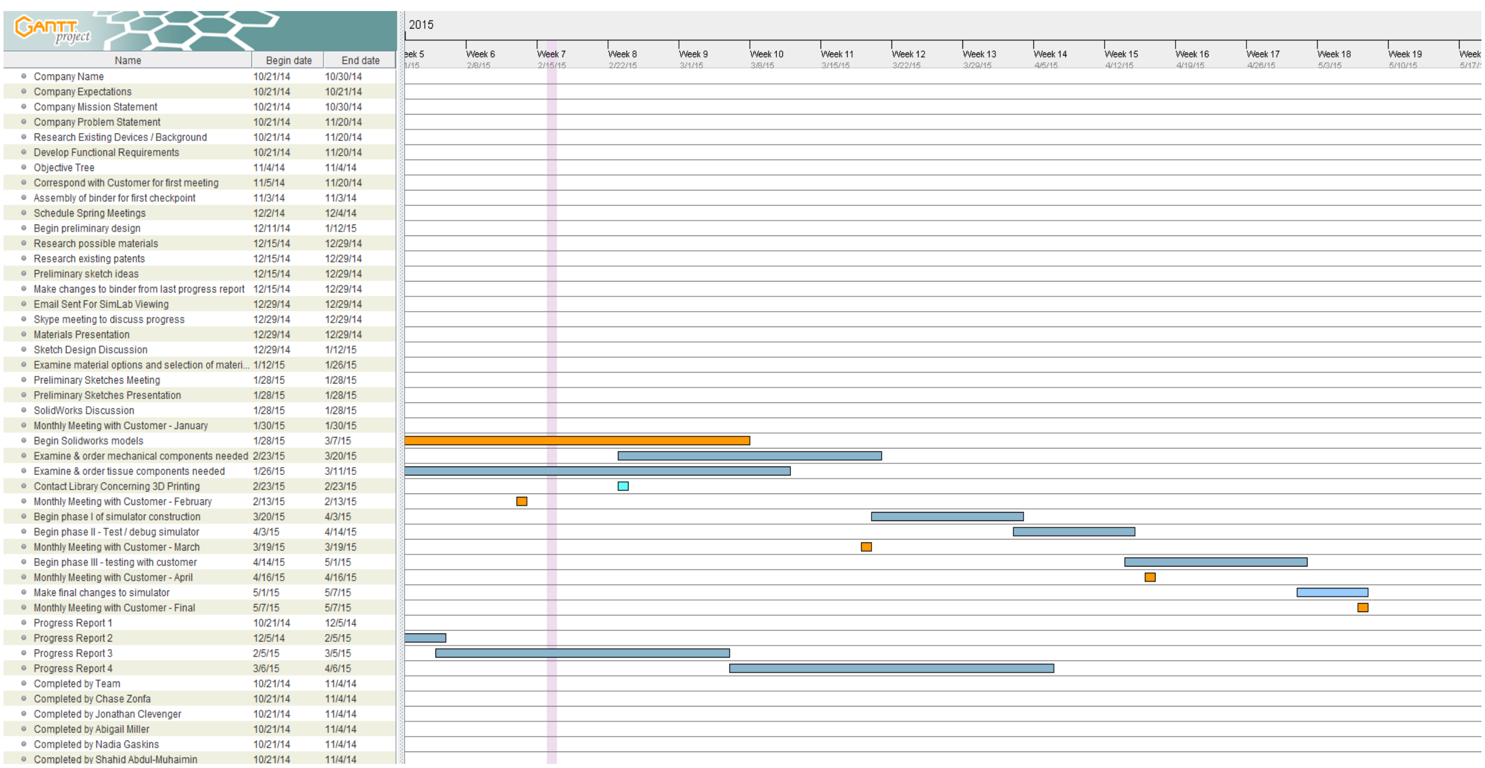
Progress Report 2 12/5/14 2/5/15


GANTT project
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2015
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Progress Report 2 12/5/14 2/5/15
Progress Report 3 2/5/15 3/5/15
Progress Report 4 3/6/15 4/6/15
Completed by Team 10/21/14 11/4/14
Completed by Chase Zonfa 10/21/14 11/4/14
Completed by Jonathan Clevenger 10/21/14 11/4/14
Completed by Abigail Miller 10/21/14 11/4/14
Completed by Nadia Gaskins 10/21/14 11/4/14
Completed by Shahid Abdul-Muhaimin 10/21/14 11/4/14

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